K100389

Handpiece Headquarters
A HENRY SCHEIN® COMPANY

AUG 12 2010

510(K) SUMMARY:

HHC- push button replacement turbine for Midwest Tradition.

510K

a- Submitted by:

HANDPIECE HEADQUARTERS
620 S. Placentia Ave.
Placentia, CA 92870
Tel. 714-579-0175 Fax. 714-579-0186

b- Contact person:

Tina Steffanie-Oak
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c- Date summary prepared: **Revised 06-10-10**

d- Device Name:

Trade or Proprietary Name: **HHC- push button replacement turbine for Midwest Tradition**

Common Name: Air-Power Dental Handpiece

Classification Name: Dental Handpiece and accessories
(21CFR 872.4200)
Class: I

Product Code: EFB "Handpiece, Air-powered, Dental"

e- Substantial Equivalency is claimed against the following device:

NSK- Replacement Turbine for Midwest Tradition Handpiece
Products of NSK NAKANISHI INC. (K971774)

f- Description of the device:

The HHC-Push button air turbine is a complete air turbine which will be offered as replacement turbine for Midwest Tradition original turbine.

High pressured air directly impacts the blade pockets of the impeller through an air intake tube located inside the handpiece body, which causes the air turbine to rotate at a high speed. The dental cutting bur connects to the turbine's shank (spindle),

which rotates at the same speed as the impeller. Cooling water flows through an inlet water tube at high pressure and blows out at an angle near the dental cutting bur to reduce temperature at cutting area.

g- Statement of Intended Use:

This HHC-Push button air turbine is intended to use with Midwest Tradition Handpiece in replacement of Midwest Tradition's original turbine.

The Midwest Tradition Handpiece with the replacement turbine is used by authorized persons in the practice of dentistry.

The replacement turbine is used in the Midwest Tradition High Speed Dental Handpiece, which is intended for removing carious material, cavity preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

h- Safety and effectiveness of the device:

The HHC-Push button air turbine is as safe and effective as the predicate device as cited above.

I – Device and Predicate Comparison Table:

Descriptive Information	Subject Device: HHC-Midwest Tradition Replacement Turbine	Predicate: NSK-Midwest Tradition Replacement Turbine
Indication of use	This HHC-Push button air turbine is intended to use in Midwest Tradition Handpiece in replacement of Midwest Tradition's original turbine. The Dental Handpiece with the replacement turbine is used by authorized persons in the practice of dentistry. This replacement turbine used in Midwest Tradition Handpiece is intended for removing carious material, cavity preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.	The devices claimed herein are the air turbines only, not the handpiece itself. The devices are intended for use in the Midwest's Quiet-air or Tradition handpieces, in place of Midwest's original turbines. The device, therefore, is, with Midwest handpiece, intended for use in general dental applications, such as cutting a tooth for crown preparation, cavity preparation, finishing the crown, inlay or the filling, etc.
Device Design:		
Operation mode	Intake air pressure 35 psi- speed 420,000 rpm. Min.	Intake air pressure 35 psi- speed 420,000 rpm Min.
Air/water ports	N/A	N/A
Fiber Optics	N/A	N/A
Type of chuck	Push button chuck (auto chuck)	Push button chuck(auto chuck)

Coupling dimensions	n/a	n/a
Accessories	n/a	n/a
Composition of material		
Spindle	440C stainless steel (see more details in attachment 4 material table)	Stainless steel
Impeller	Aluminum (see more details in attachment 4 material table)	Aluminum
Bearings	440C stainless steel (see more details in attachment 4 material table)	Stainless steel
O-ring	Buna (see more details in attachment 4 material table)	Buna
Technical specification		
Chuck	Push button chuck spindle Outside diameter: 0.125" Chuck length: 0.425" Actuator height: 0.034"	Push Button: Outside diameter: 0.125" Chuck length: 0.435" Actuator height: 0.038"
Light intensity	n/a	n/a
Bur extraction force	5 lbs Min. push and pull forces/ 100 inspection using ONMI gauge/ per specification indicated on drawing	5 lbs Min. push and pull forces- tested on predicate device
Air pressure	35 psi. recommended	35 psi.
Water pressure	2 bar	2 bar
Speed Rpm	420,000 rpm. Min.	420,000 rpm. Min.
Hose connection	n/a	n/a
Conformance standard for shanks	Meet I.S.O standard Shank diameter from 0.0625" to 0.0630"	Meet I.S.O standard shank
Lubricant		
n/a	Dental lubricated oil	Lubricant recommended but specific type and it is not indicated in labeling.

J – Performance Data:

The HHC-Push button air turbine performance tests were carried out to evaluate it against the predicate device. In all instances the HHC-Push button air turbine functioned as intended, results observed were as expected, and was determined to have comparable performance and safety as compared to the predicate.

No clinical data was required.

K -Conclusion:

Based on the information in the notification Handpiece Headquarters believes that this HHC-Push button air turbine is substantially equivalent to the claimed predicate device. (NSK- Replacement Turbine for Midwest Tradition Handpiece Products of NSK-NAKANISHI INC. (K971774))

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tina Steffanie-Oak
Senior Regulatory Specialist
Handpiece Headquarters
620 S. Placentia Avenue
Placentia, California 92870

AUG 12 2010

Re: K100389
Trade/Device Name: HHC- push button replacement turbine for Midwest Tradition
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: II
Product Code: EFB
Dated: August 6, 2010
Received: August 6, 2010

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

AUG 12 2010

510(k) Number (if known): K100389

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Indications for Use:

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The Dental Handpiece with the HHC- replacement turbine is used by authorized persons in the practice of dentistry.

The HHC-replacement turbine is used in the Midwest Tradition High Speed Dental Handpiece, which is intended for removing carious material, cavity preparations, finishing tooth preparations, reducing hard tooth structures, restorations and polishing teeth.

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lon Mixley for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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